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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/646,399	11/01/2000	Carole Ciolina	ST98008A	8666

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EXAMINER

SULLIVAN, DANIEL M

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 06/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/646,399

Applicant(s)

CIOLINA ET AL.

Examiner

Daniel M Sullivan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-42 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

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DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-9 and 14-37, drawn to a vector comprising a double-stranded DNA molecule and at least one oligonucleotide coupled to a targeting signal and capable of forming a triple helix with a specific sequence present in the double-stranded DNA molecule, wherein said specific sequence is poly-GAA and the oligonucleotide comprises poly CTT.

Group II, claim(s) 1-7, 10 and 14-37, drawn to a vector comprising a double-stranded DNA molecule and at least one oligonucleotide coupled to a targeting signal and capable of forming a triple helix with a specific sequence present in the double-stranded DNA molecule, wherein said specific sequence comprises SEQ ID NO: 3.

Group III, claim(s) 1-7, 11 and 14-37, drawn to a vector comprising a double-stranded DNA molecule and at least one oligonucleotide coupled to a targeting signal and capable of forming a triple helix with a specific sequence present in the double-stranded DNA molecule, wherein said specific sequence comprises SEQ ID NO: 6.

Group IV, claim(s) 1-7, 12 and 14-37, drawn to a vector comprising a double-stranded DNA molecule and at least one oligonucleotide coupled to a targeting signal and capable of forming a triple helix with a specific sequence present in the double-stranded DNA molecule, wherein said specific sequence comprises SEQ ID NO: 8.

Group V, claim(s) 1-7, 12 and 14-37, drawn to a vector comprising a double-stranded DNA molecule and at least one oligonucleotide coupled to a targeting signal and capable of forming a triple helix with a specific sequence present in the double-stranded DNA molecule, wherein said specific sequence comprises SEQ ID NO: 10.

Group VI, claim(s) 1-7 and 13-37, drawn to a vector comprising a double-stranded DNA molecule and at least one oligonucleotide coupled to a targeting signal and capable of forming a triple helix with a specific sequence present in the double-stranded DNA molecule, wherein said specific sequence comprises SEQ ID NO: 9.

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Group VII, claim(s) 38, drawn to the use of the vector of Groups I-VI for the manufacture of a medicament.

Group VIII, claim(s) 39, drawn to a method of transfecting nucleic acids into cells comprising making an oligonucleotide-targeting signal chimera, bringing the chimera into contact with a double stranded DNA to form a triple helix and bringing cells into contact with the triple helical complex.

Group IX, claim(s) 40, drawn to a method of treating diseases comprising administering a vector according to groups I-VI.

Group X, claim(s) 41 and 42, drawn to a recombinant cell containing the vector according to Groups I-VI.

Each of Groups I-VI are further restricted to a single named targeting signal selected from the group set forth in claims 21-25, a single named transfecting agent selected from the group set forth in claims 28 and 29 and a single named adjuvant selected from those set forth in claims 30-33.

The inventions listed as Groups I-X and the species set forth in claims 21-25, 28-29 and 30-33 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

According to PCT Rule 13.2, unity of invention exists only when the shared same or corresponding technical feature is a contribution over the prior art. The inventions listed as Groups I-X and the species set forth in claims 21-25, 28-29 and 30-33 do not relate to a single general inventive concept because they lack the same or corresponding special technical feature. The technical feature shared by Groups I-X is a vector comprising a double-stranded DNA molecule and at least one oligonucleotide coupled to a targeting signal and capable of forming a triple helix with a specific sequence present in the double-stranded DNA molecule.

However, Felgner *et al.* U.S. Patent No. 6,165,720 (effective filing date 18 September 1997) teaches a vector comprising a double-stranded DNA molecule and at least one oligonucleotide coupled to a targeting signal and capable of forming a triple helix with a specific sequence present in the double-stranded DNA molecule (see especially the second full paragraph in column 3, the paragraph bridging columns 3-4 and the third full paragraph in column 2). Thus, the teachings of Felgner *et al.* anticipate the technical feature that links the instant Groups I-X. Likewise, the teachings of Felgner *et al.* anticipate the general technical feature of a targeting signal, which unites the species of claims 21-25 (see especially lines 41-45 in column 3), the general technical feature of a transfecting agent that links the species of claims 28 and 29 (see especially lines 18-19 in column 4), and the adjuvant of claims 30-33 (see especially line 6 in column 16). Thus, the identified groups lack a unifying same or corresponding general inventive concept.

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The special technical feature of Group I is considered to be a specific sequence comprising poly-GAA and an oligonucleotide comprising poly CTT

The special technical feature of Group II is considered to be a specific sequence comprising SEQ ID NO: 3

The special technical feature of Group III is considered to be a specific sequence comprises SEQ ID NO: 6

The special technical feature of Group IV is considered to be a specific sequence comprising SEQ ID NO: 8

The special technical feature of Group V is considered to be a specific sequence comprising SEQ ID NO: 10

The special technical feature of Group VI is considered to be a specific sequence comprising SEQ ID NO: 9

The special technical feature of Group VII is considered to be the manufacture of a medicament comprising the disclosed vectors.

The special technical feature of Group VIII is considered to be making an oligonucleotide-targeting signal chimera, bringing the chimera into contact with a double stranded DNA to form a triple helix and bringing cells into contact with the triple helical complex.

The special technical feature of Group IX is considered to be therapeutic administration of a vector according to groups I-VI.

The special technical feature of Group X is considered to be a recombinant cell containing the vector according to Groups I-VI.

The special technical feature of the targeting signal species set forth in claims 21-25 are those structural and functional properties that are unique to each one.

The special technical feature of the transfecting agents of claims 28 and 29 are those structural and functional properties that are unique to each one.

The special technical feature of the adjuvants of claims 30-33 are those structural and functional properties that are unique to each one.

Accordingly, Groups I-X and the species set forth in claims 21-25, 28-29 and 30-33 do not relate to a single general inventive concept.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the

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product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 571-272-0779. The examiner can normally be reached on Monday through Thursday 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

DMS

Anne-Marie Falk
ANNE-MARIE FALK, PH.D
PRIMARY EXAMINER